K083157

510(k) Summary

SEP 29 2009

1. Submitter Information

Owner:	H.S. Hospital Service S.p.A. Via A. Vacchi, 24/26 04011 Aprilia (LT) – Itay tel.: 0039 06 9201961 – fax: 0039 0692727871
Contact person:	US representative H-S Medical, Inc. Mr. Lucio Improta 6600 W. Rogers Circle – Suite 1 & 2 Boca Raton, FL 33487 Tel.: (561)443-3321 - Fax: (561)443-3532 email: hsmedicalinc@aol.com
Date summary prepared:	September 17th, 2009

2. Name of Device

Trade or Proprietary Name:	HS AMICA
Common or Usual Name:	Microwave Tissue Coagulation System
Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories

3. Predicate Device

The HS AMICA is substantially equivalent in function and intended use to the following legally marketed device: VivaWave Microwave Ablation System (K053535) and VivaTip Microwave Ablation Probe (K032702). The HS AMICA pump is equivalent to that of Cool-Tip RF Ablation System (K042216).
Though operating at different microwave frequencies (915 MHz for Vivawave and 2450 MHz for HS AMICA, respectively), both system achieve the thermoablation of selected soft tissues located inside the human body through the local delivery of microwave energy.
Both systems are composed by a microwave generator, a single use interstitial probe - capable of penetrating into tissues and delivering microwave energy to target tissues through its active distal tip- and by a peristaltic pump for continuous water circulation inside the probe -for applicator cooling-.

Both systems allow the operator to select the microwave output power level and the procedure time, as required by the specific application. In both systems the microwave power output is started manually by the operator and may either be stopped manually at any time by the operator, or deactivated automatically when the selected procedure time has elapsed. Both systems exhibit software-based electronic control for comfortable operator's setting, handling and monitoring of the ablation procedure. Both systems are endowed with a variety of software and hardware alarms and protections to prevent excessive energy delivery to tissues, overheating of the probe insertion track and other possible criticalities.
The two systems differ in the overall coagulative performance and in the probe and microwave source design, structure and architecture.

4. Device Description

HS AMICA (Apparatus for MICrowave Ablation) is an integrated system for interstitial thermoablation of soft tissues through controlled emission of microwaves.
The system is composed by three interactive devices, namely:
- AMICA-GEN: a digitally controlled microwave power source, operating at 2450 MHz and delivering up to 100 W CW (continuous wave); it features a single output channel
- AMICA-PROBE: an interstitial single-use coaxial microwave applicator, fed by AMICA-GEN;
- AMICA-PUMP: a peristaltic pump for convective applicator cooling through continuous circulation of liquid coolant, fully controlled by AMICA-GEN;

5. Intended Use

HS AMICA is intended for coagulation (thermoablation) of soft tissues; not for use in cardiac procedures.

6. Summary of Technological Characteristics

The HS AMICA has the same basic technological characteristics as the predicate device.

HS AMICA achieves soft tissue coagulation by means of a controlled and confined delivery of microwave energy, locally inducing a temperature increase which leads to cellular necrosis.

AMICA-GEN microwave output is a true sinusoidal wave at 2450 MHz, ranging in power from 0 to 100W, suitable for standard thermoablative procedures on almost any type of human tissue. AMICA-GEN has one microwave output channel. AMICA-GEN not only feeds microwave power to AMICA-PROBE –in *manual mode*, that is delivering an amount of

microwave power set by the user, or in *automatic mode*, that is reaching and maintaining a user selected temperature value by self-regulation of the microwave output-, but also serves as user interface for operative parameters setting (ablation time, power to be delivered or target temperature, maximum allowed temperature), continuously performs and displays measurements of the most significant ablation quantities (elapsed ablation time, delivered microwave power, amount of reflected power in % of delivered power, probe temperature), executes safety checks (presence and fine connection of all peripherals, correct functioning of the power supply unit and of the microwave module, monitoring of measured values), treats errors and alert states providing appropriate acoustic and visual feedback to the user, automatically suspends microwave output in case of emergency and, finally, has full control over the peristaltic pump AMICA-PUMP.

AMICA-GEN is a solid state microwave source, capable of generating microwave power through field effect gallium arsenide transistors driven at 12 VDC: no high voltage parts are employed and maximum electrical safety is guaranteed both to patients and operators.

AMICA-GEN has an essential and intuitive user interface simply based on a touchscreen LCD and a rotary knob for selection and confirmation of settings.

AMICA-PROBE is built around a microwave coaxial antenna operated at 2.45GHz (same frequency as commercial microwave ovens), lodged into a stainless steel needle for direct percutaneous insertion: it is thus indicated for interstitial thermoablations. The applicator features:

1) a patented miniaturized quarter-wave coaxial choke superimposed to the antenna, which effectively traps reflected microwaves (that is, the portion of delivered power not absorbed by target tissues and propagating backwards along the applicator axis): this mini-choke eliminates uncontrolled back heating effects due to reflections, while keeping the applicator transversal size at a minimum; truly minimal invasiveness and accurate control over the ablated region size and shape are, thus, jointly warranted;
2) a sharp stainless steel pyramidal point for straightforward tissue penetration;
3) an integrated hydraulic cooling system to remove the heat dissipated due to ohmic losses along the antenna coaxial feeding line: it avoids overheating of the applicator walls and maximizes the microwave power level handled by the applicator for a given antenna size;
4) an embedded thermocouple sensor for temperature monitoring inside the applicator;
5) an embedded "Write Once Read Many" digital memory chip for software identification of the applicator (factory data ensuring product traceability) and for enhanced safety of use (compatibility checks, protection against improper use or tampering, self-limiting of maximum deliverable power, automatic inhibition of yet used or expired applicators);

Finally, the peristaltic pump AMICA-PUMP is a peripheral device fed and controlled directly by AMICA-GEN, needless of any manual intervention by the user (except for the initial placing of the coolant inlet tubing).

External devices (such as a PC for remote control or data downloading) may be daisy chained to AMICA-PUMP and straightforward communicate with AMICA-GEN.

All materials in contact with patients used in manufacturing AMICA-PROBE are suitable for this purpose and have been used in numerous previously cleared procedures.

Performance testing was executed to ensure that HS AMICA functions as intended and meets design specifications. Sufficient data were obtained to show that the device meets safety and effectiveness criteria and is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

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SEP 29 2009

Re: K083157
Trade/Device Name: HS AMICA
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: NEY
Dated: September 14, 2009
Received: September 14, 2009

Dear Mr. Improta:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

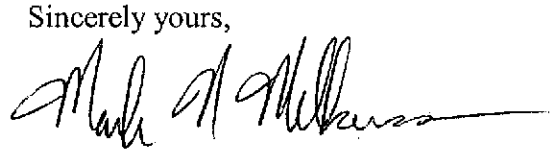
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number:	K083157
Device Name:	HS AMICA
Indications for Use:	HS AMICA is intended for coagulation (thermoablation) of soft tissues. Not for use in cardiac procedures.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for mkm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K083157